

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

U.S. Patent No: 7,037,721 B1

Issued: May 2, 2006

Inventor: John J. Wille, Jr.

Serial No.: 09/694,393

Entitled: PROTEIN-FREE DEFINED MEDIA FOR THE GROWTH OF
NORMAL HUMAN KERATINOCYTES

Examiner: Leon B. Lankford, Jr.

Group Art Unit: 1651

Docket No.: HYG 1194-011D

Commissioner for Patents
Attention: Certificate of Correction Branch
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8 (A)

I hereby certify that this correspondence is being electronically transmitted on May 11, 2006, to the United States Patent and Trademark Office by EFS-Web.


Vickie D'Alessandro, Paralegal

**REQUEST FOR CERTIFICATE OF CORRECTION PURSUANT
TO 37 C.F.R. 1.322 AND 37 C.F.R. 1.323**

Transmitted herewith is a Certificate of Correction for U.S. Patent No. 7,037,721 B1, which issued on May 2, 2006. Upon reviewing the patent, the patentee noted that the following typographical errors were made by the Patent and Trademark Office, which should be corrected as follows:

In section (56), please add the following U.S. Patent Documents initialed by the Examiner on September 20, 2001 and inadvertently not cited in the patent as follows:

4,009,282	02/22/77	Voorhees	514/573
4,016,036	04/05/77	Green, et al.	195/1.8
4,088,756	05/09/78	Voorhees	514/047
4,201,788	05/06/80	Voorhees, et al.	514/081
4,209,315	06/10/80	Voorhees, et al.	514/047
4,304,866	12/08/81	Green, et al.	435/240
4,485,096	11/27/84	Bell	424/95
4,673,649	06/16/87	Boyce, et al.	435/240
4,940,666	07/10/90	Boyce, et al.	435/240.2
5,232,848	08/03/93	Wolfe, et al.	435/240.31
5,292,655	03/08/94	Wille, Jr.	435/240.2
5,326,699	07/05/94	Torishima, et al.	435/240.2
5,328,844	07/12/94	Moore	435/240.31
5,604,346	8/86	Bell, et al.	435/1
5,683,307	11/11/97	Wille, Jr.	435/405
5,834,312	11/10/98	Wille, Jr.	435/405
5,871,909	02/16/99	ANG.strom, et al.	435/006
6,063,606	05/2000	Martin, et al.	435/189

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"Production of Epidermal Sheets in a Serum Free Culture System: A further appraisal of the role of extracellular calcium," *Journal of Dermatological Science*, 3, Boisseau, et al., Elsevier Science Publishers V.V. (1992) 111-120.

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“Reversible Inhibition of Normal Human Prokeratinocyte Proliferation of Type β
Transforming Growth Factor-Growth Inhibitor in Serum-free Medium,” Shipley, et al.,
Cancer Research 46, 2068-2071, April, 1986.

“Serum-Free Cultures of Normal Human Gingival Keratinocytes (HGK),” Wille, et
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Kamata, et al. "Growth-inhibitory effects of epidermal growth factor and overexpression of its receptors on human squamous cell carcinomas in culture," *Cancer Res.* 46(4 Pt 1):1648-53 April 1986 (Medline Abstract).

In column 7, line 20, please delete "0.01" and insert-- 0.1 --.

In column 10, line 52, please delete "speed-centrifugation," and insert-- speed centrifugation --.

In column 12, in Table 1, please delete "Pyridoxal.HCl" and insert -- Pyridoxal·HCl --.

In column 12, in Table 1, please delete "Thiamine.HCl" and insert -- Thiamine·HCl --.

In column 12, in Table 1, please delete "Calcium chloride.2H₂O" and insert -- Calcium chloride·2H₂O --.

In column 12, in Table 1, please delete "Magnesium chloride.6H₂O" and insert-- Magnesium chloride·6H₂O --.

In column 12, in Table 1, please delete "Ferrous sulfate.7H₂O" and insert -- Ferrous sulfate·7H₂O --.

In column 12, in Table 1, please delete "Manganese Sulfate.5H₂O" and insert -- Manganese Sulfate·5H₂O --.

In column 12, in Table 1, please delete "Sodium Silicate.9H₂O" and insert -- Sodium Silicate·9H₂O --.

In column 12, in Table 1, please delete "Ammonium Molybdate.4H₂O" and insert - - Ammonium Molybdate·4H₂O --.

In column 12, in Table 1, please delete "Nickel Chloride.6H₂O" and insert -- Nickel Chloride·6H₂O --.

In column 12, in Table 1, please delete "Zinc Chloride.7H₂O" and insert -- Zinc Chloride·7H₂O --.

In column 12, in Table 1, please delete "Sodium Acetate.3H₂O" and insert-- Sodium Acetate·3H₂O --.

In column 14, in line 19, please delete "(J".

In column 16, in line 21, please delete "HPO.sub.4.7H.sub.2O)" and insert--
HPO.sub.4.7H.sub.2 O) --.

Upon reviewing the patent, the patentee noted typographical errors on the first page of the patent. Accordingly, the required fee of \$100.00 is enclosed. It is evident after a review of information previously submitted that this information should be corrected as follows:

In section 73, please delete "Hy-Gene Biomedical, Inc., Charlotte, NC (US)" and insert -- Hy-Gene Biomedical Corporation, Ventura, CA (US) --.

In section 74, please delete "Standley & Gilcrest LLP" and insert -- Standley Law Group LLP --.

Approval of the Certificate of Correction respectfully is solicited.

Respectfully submitted,

Date: May 11, 2006

By: Carol G. Stovsky
Carol G. Stovsky
Registration No. 42,171
Standley Law Group LLP
495 Metro Place South, Suite 210
Dublin, Ohio 43017-5319
Telephone: 614-792-5555
Facsimile: 614-792-5536

UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 19

PATENT NO. : 7,037,721 B1

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In section (56), please add the following U.S. Patent Documents initialed by the
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4,016,036	04/05/77	Green, et al.	195/1.8
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495 Metro Place South, Suite 210, Dublin, Ohio 43017-5319

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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"Effects of Growth Factors, Hormones, Bacterial Lipopolysaccharides, and Lipotechoic Acids on the Clonal Growth of Normal Ureteral Epithelial Cells in Serum-Free Culture," Wille, et al., *Journal of Cellular Physiology*, 150:52-58 (1992).

"Integrated Control of Growth and Differentiation of Normal Human Prokeratinocytes Cultured in Serum-Free Medium: Clonal Analyses, Growth Kinetics, and Cell Cycle Studies," Wille, Jr., et al., *Journal of Cellular Physiology*, 121:31-44 (1984).

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Carol G. Stovsky, Reg. No. 42,171
Standley Law Group LLP
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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**

Page 6 of 19

PATENT NO. : 7,037,721 B1
APPLICATION NO.: 09/694,393
ISSUE DATE : May 2, 2006
INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

"Propagation of Differentiating Normal Human Tracheobronchial Epithelial Cells in Serum-Free Medium," Chopra, et al., *Journal of Cellular Physiology* 130: 173-181 (1987).

"Reversible Inhibition of Normal Human Prokeratinocyte Proliferation of Type β Transforming Growth Factor-Growth Inhibitor in Serum-free Medium," Shipley, et al., *Cancer Research* 46, 2068-2071, April, 1986.

"Serum-Free Cultures of Normal Human Gingival Keratinocytes (HGK)," Wille, et al., *Journal of Dental Research*, 68, 1019, #1216.

"Two Functionally Distinct Classes of Growth Arrest States in Human Prokeratinocytes that Regulate Clonogenic Potential," Pittelkow, et al., *Journal of Investigative Dermatology*, Vol. 4, April, 1986, pp. 410-417.

Moses, et al. "Growth & Differentiation of Cells in Defined Enviroment (1985) pp. 373-378.

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PATENT NO. : 7,037,721 B1

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Booyens, et al, "Prostaglandins Leukot. Md.," Jul. 1984, 15 (1) pp. 15-33 (Biosis Abstract #84298492).

The Merck Index, 10th edition, 1983, p. 1172.

Boyce & Ham, *J. Invest. Dermatol.* 81:33-40, 1983 Ca-Reg. differentiation of normal human epid. Keratin In chemical & serum defined Med.

"All-Trans Retinoic Acid Stimulates Growth of Adult Human Keratinocytes Cultured in Growth Factor-Deficient Medium, Inhibits Production of Thrombosondin in Fibronectin, and Reduces Adhesion," Varani, et al. *The Society for Investigative Dermatology, Inc.*, 0022-202X/89/S03.50 (1989).

Rikimaru, et al. "Growth of malignant and nonmalignant human squamous cells in a protein-free defined medium, *In Vitro Cell Dev. Biol.*, 26(9):849-56, Sept. 1990 (Medline Abstract).

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Page 8 of 19

PATENT NO. : 7,037,721 B1 .

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Diaz, et al. "Regulation of vascular endothelial growth factor expression in human keratinocytes by retinoids, *J. Biol. Chem.* 275(1):642-50, Jan. 7, 2000 (Medline Abstract).

Stoll, et al. "Retinoid regulation of heparin-binding EGF-like growth factor gene expression in human keratinocytes and skin," *Exp. Dermatol.* 7(6):3917, Dec. 1998 (Medline Abstract).

Marcello, et al., "Retinoic acid stimulates essential fatty acid-supplemented human keratinocytes in culture," *J. Invest. Dermatol.*, 108(5):758-62 May 1997 (Medline Abstract).

Jetten "Multi-stage program of differentiation in human epidermal keratinocytes: regulation by retinoids," *J. Invest. Dermatol.*, 85(5):44S-46S Nov. 1990 (Medline Abstract).

Jee, et al., "Growth and characterization of normal human keratinocytes in F12 serum-free medium," *J. Formos Med. Assoc.* 89(7):559-64 July 1990 (Medline Abstract).

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PATENT NO. : 7,037,721 B1

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Varani, "Preservation of human skin structure and function in organ culture," *Histol. Histopathol.* 13(3):775-83 July 1998 (Medline Abstract).

Siegenthaler, et al. "Retinol and retinal metabolism. Relationship to the state of differentiation of cultured human keratinocytes," *Biochem J.* 268(2):371-8 June 1, 1990 (Medline Abstract).

Lachgar, et al. "Inhibitory effects of retinoids on vascular endothelial growth factor production by cultured human skin keratinocytes," *Dermatology* 199 Suppl. 1:25-7 1999 (Medline Abstract).

Imanishi, et al. "Growth factors: importance in wound healing and maintenance of transparency of the cornea," *Prog. Retin Eye Res.* 19(1):113-29 Jan. 2000 (Medline Abstract).

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Page 10 of 19

PATENT NO. : 7,037,721 B1

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Johnson, et al. "Persistence of fetal bovine serum proteins in human keratinocytes,"
J. Burn Care Rehabil., 11(6) 504-9 Nov.-Dec. 1990 (Medline Abstract).

Schwartz "In vitro growth changes of oral human keratinocytes after treatment with
carotenoids, retinoid, and/or DMBA," *Nutr. Cancer*, 33(1):58-68 1999 (Medline Abstract).

Sass, et al. "Metabolism of topical retinaldehyde and retinol by mouse skin in vivo:
predominant formation of retinyl esters and identification of 14-hydroxy-4, 4-retro-retinol,"
Exp. Dermatol. 5(5):267-71, Oct. 1996 (Medline Abstract).

Marikar, et al. "Retinoic acid receptors regulate expression of retinoic acid 4-
hydroxylase that specifically inactivates all-trans retinoic acid in human keratinocyte HaCaT
cells," *J. Invest. Dermatol.*, 111(3):434-9 Sept. 1998 (Medline Abstract).

Griffiths, et al. "Short-term retinoic acid treatment increases in vivo, but decreases in
vitro, epidermal transglutaminase-K enzyme activity and immunoreactivity," *J. Invest
Dermatol.* 99(3):283-8 Sept. 1992 (Medline Abstract).

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PATENT NO. : 7,037,721 B1

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Duell, et al. "Human skin levels of retinoic acid and cytochrome P-450-derived 4-hydroxyretinoic acid after topical application of retinoic acid in vivo compared to concentrations required to stimulate retinoic acid receptor-mediated transcription in vitro," *J. Clin. Invest.* 90(4): 1269-74 Oct. 1992 (Medline Abstract).

Duell, et al. "Unoccluded retinol penetrates human skin in vivo more effectively than unoccluded retinyl palmitate or retinoic acid," *J. Invest. Dermatol.* 109(3):301-5 Sept. 1997 (Medline Abstract).

Kang, et al. "Liarozole inhibits human epidermal retinoic acid 4-hydroxylase activity and differentially augments human skin responses to retinoic acid and retinol in vivo," *J. Invest. Dermatol.* 107(2):183-7 Aug. 1996 (Medline Abstract).

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**UNITED STATES PATENT AND TRADEMARK OFFICE
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Page 12 of 19

PATENT NO. : 7,037,721 B1
APPLICATION NO.: 09/694,393
ISSUE DATE : May 2, 2006
INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Kurlandsky, et al; "Auto-regulation of retinoic acid biosynthesis through regulation of retinol esterification in human keratinocytes," *J. Biol. Chem.* 271 (26):15346-52 June 28, 1996 (Medline Abstract).

Varani, et al. "A direct comparison of pharmacologic effects of retinoids on skin cells in vitro and in vivo," *Skin Pharmacol.* 4(4):254-61 1991 (Medline Abstract).

Varani, et al. "Retinoic acid stimulation of human dermal fibroblast proliferation is dependent on suboptimal extracellular Ca²⁺ concentration," *Am. J. Pathol.* 136(6):1275-81 June 1990 (Medline Abstract).

Varani, et al. "All-trans retinoic acid stimulates growth and extracellular matrix production in growth-inhibited cultured human skin fibroblasts," *J. Invest. Dermatol.* 94(5):717-23 May 1990 (Medline Abstract).

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Page 13 of 19

PATENT NO. : 7,037,721 B1
APPLICATION NO.: 09/694,393
ISSUE DATE : May 2, 2006
INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Wang, et al. "Ultraviolet irradiation of human skin causes functional vitamin A deficiency, preventable by all-trans retinoic acid pre-treatment," *Nat. Med.* 5(4):418-22 April 1999 (Medline Abstract).

Xiao, et al. "Identification of heparin-binding EGF-like growth factor as a target in intercellular regulation of epidermal basal cell growth by suprabasal retinoic acid receptors," *EMBO J.* 18(6):1539-48 March 15, 1999 (Medline Abstract).

Griffiths, et al. "Mechanisms of action of retinoic acid in skin repair," *Br. J. Dermatol.* 127 Suppl 4:21-4 Sept. 1992 (Medline Abstract).

Varani, et al. "Induction of proliferation of growth-inhibited keratinocytes and fibroblasts in monolayer culture by sodium lauryl sulfate: comparison with all-trans retinoic acid," *J. Invest. Dermatol.* 97(5):917-21 Nov. 1991 (Medline Abstract).

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Page 14 of 19

PATENT NO. : 7,037,721 B1

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Fligiel, et al. "Modulation of growth in normal and malignant melanocytic cells by all-trans retinoic acid," *J. Cutan Pathol.* 19(1):27-33 Feb. 1992 (Medline Abstract).

Varani, et al. "Inhibition of epithelial cell adhesion by retinoic acid. Relationship to reduced extracellular matrix production and alterations in Ca²⁺ levels," *Am. J. Pathol.* 138(4):887-95 April 1991 (Medline Abstract).

Varani, et al. "Modulation of Ca²⁺ levels in keratinocytes by all-trans retinoic acid," *Pathobiology* 60(2):93-9 1992 (Medline Abstract).

Varani, et al. "Molecular mechanisms of intrinsic skin aging and retinoid-induced repair and reversal," *J. Invest. Dermatol. Symp. Proc.* 3(1):57-60 Aug. 1998 (Medline Abstract).

Tavakkol, et al. "Expression of growth hormone receptor, insulin-like growth factor 1 (IFG-1) and IFG-1 receptor mRNA and proteins in human skin," *J. Invest. Dermatol.* 99(3):343-9 Sept. 1992 (Medline Abstract).

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PATENT NO. : 7,037,721 B1
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ISSUE DATE : May 2, 2006
INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Fisher, et al. "Molecular mechanisms of retinoid actions in skin," *FASEB J.*

10(9):1002-13 July 1996 (Medline Abstract).

Sasaki, et al. "Enhancement by 1 alpha,25-dihydroxyvitamin D3 of chemically induced transformation of BALB 3T3 cells without induction of ornithine decarboxylase or activation of protein kinase C1," *Cancer Res.* 46(2):604-10 Feb. 1986 (Medline Abstract).

Kamata, et al. "Growth of normal oral keratinocytes and squamous cell carcinoma cells in a novel protein-free defined medium," *In Vitro Cell Dev. Biol Anim.* 35(10):63-41 Nov.-Dec. 1999 (Medline Abstract).

Goi, et al "DNA damage-associated dysregulation of the cell cycle and apoptosis control in cells with germ-line p53 mutation," *Cancer Res.* 57(10):1895-902 May 15, 1997 (Medline Abstract).

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PATENT NO. : 7,037,721 B1

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Kurata, et al. "Effect of eicosapentaenoic acid and arachidonic acid on mouse peritoneal exudate cells and its characteristics," *Yakugaku Zasshi* 106(11):1040-4 Nov. 1986 (Japanese language—copy not available) (Medline report).

Kamata, et al. "Growth-inhibitory effects of epidermal growth factor and overexpression of its receptors on human squamous cell carcinomas in culture," *Cancer Res.* 46(4 Pt 1):1648-53 April 1986 (Medline Abstract).

In column 7, line 20, please delete "0.01" and insert-- 0.1 --.

In column 10, line 52, please delete "speed-centrifugation," and insert-- speed centrifugation --.

In column 12, in Table 1, please delete "Pyridoxal.HCl" and insert -- Pyridoxal·HCl

--.

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ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 12, in Table 1, please delete "Thiamine.HCl" and insert -- Thiamine·HCl

--.

In column 12, in Table 1, please delete "Calcium chloride.2H₂O" and insert --
Calcium chloride·2H₂O --.

In column 12, in Table 1, please delete "Magnesium chloride.6H₂O" and insert--
Magnesium chloride·6H₂O --.

In column 12, in Table 1, please delete "Ferrous sulfate.7H₂O" and insert --
Ferrous sulfate·7H₂O --.

In column 12, in Table 1, please delete "Manganese Sulfate.5H₂O" and insert --
Manganese Sulfate·5H₂O --.

In column 12, in Table 1, please delete "Sodium Silicate.9H₂O" and insert --
Sodium Silicate·9H₂O --.

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495 Metro Place South, Suite 210, Dublin, Ohio 43017-5319

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**UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION**Page 18 of 19

PATENT NO. : 7,037,721 B1

APPLICATION NO.: 09/694,393

ISSUE DATE : May 2, 2006

INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 12, in Table 1, please delete "Ammonium Molybdate.4H₂O" and insert -
- Ammonium Molybdate·4H₂O --.

In column 12, in Table 1, please delete "Nickel Chloride.6H₂O" and insert -- Nickel
Chloride·6H₂O --.

In column 12, in Table 1, please delete "Zinc Chloride.7H₂O" and insert -- Zinc
Chloride·7H₂O --.

In column 12, in Table 1, please delete "Sodium Acetate.3H₂O" and insert--
Sodium Acetate·3H₂O --.

In column 14, in line 19, please delete "(J".

In column 16, in line 21, please delete "HPO.sub.4.7H.sub.2O)" and insert--
HPO.sub.4.7H.sub.2 O) --.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

Carol G. Stovsky, Reg. No. 42,171
Standley Law Group LLP
495 Metro Place South, Suite 210, Dublin, Ohio 43017-5319

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Page 19 of 19

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ISSUE DATE : May 2, 2006
INVENTOR(S) : John J. Wille, Jr.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In section 73, please delete "Hy-Gene Biomedical, Inc., Charlotte, NC (US)" and insert -- Hy-Gene Biomedical Corporation, Ventura, CA (US) --.

In section 74, please delete "Standley & Gilcrest LLP" and insert -- Standley Law Group LLP --.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

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